



NEWS RELEASE

Arcus Biosciences Announces Clinical Trial Collaboration and Supply Agreement to Evaluate Casdatifan in Combination with PD-L1/VEGF-A Bispecific Immunomodulator to Treat Kidney Cancer

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- This collaboration aims to develop a novel treatment regimen that delivers more sustained tumor control in kidney cancer, a cancer of high unmet medical need

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE: RCUS), a clinical-stage, global biopharmaceutical company focused on developing differentiated molecules and combination therapies for people with cancer and inflammatory and autoimmune diseases, today announced a clinical trial collaboration and supply agreement with Bristol Myers Squibb (NYSE: BMY, "BMS"). Under the agreement, Arcus will supply casdatifan, the company's investigational small-molecule HIF-2a inhibitor, to be evaluated as part of the BMS-sponsored Phase 1/2 ROSETTA RCC-208 clinical trial. This trial evaluates pumitamig (BNT327/BMS986545), an investigational PD-L1/VEGF-A bispecific antibody, being jointly developed by BioNTech and Bristol Myers Squibb, alone or in combination with other potential treatment options in advanced renal cell carcinoma (RCC).

As part of this clinical trial collaboration, casdatifan combinations will be added as two new arms of ROSETTA RCC-208. Each company will retain development and commercial rights to their respective assets, and the agreement is mutually non-exclusive.

"We believe casdatifan can transform the treatment paradigm in kidney cancer, and our development strategy is designed to generate evidence needed to establish casdatifan as a backbone therapy so that every patient has the opportunity to benefit from casdatifan across each line of therapy," said Terry Rosen, Ph.D., chief executive officer

of Arcus. "HIF-2a inhibition, PD-L1 and VEGF-A blockade are validated mechanisms in the treatment of kidney cancer with a strong biologic rationale for combination. This strategic collaboration with BMS is a top priority for Arcus in order to potentially deliver an additional effective TKI-free option in the first-line setting."

This collaboration is part of Arcus's holistic development strategy that is intended to provide physicians and patients with: 1) a casdatifan-based and only HIF-2a inhibitor-inclusive TKI-sparing first-line treatment; 2) a casdatifan-based TKI-inclusive first-line regimen; 3) a second-line HIF-2a inhibitor treatment that builds on the second-line standard-of-care TKI, cabozantinib; and 4) a late-line therapy that has been clinically validated to also provide benefit in patients previously treated with a HIF-2a inhibitor-based therapy.

About Casdatifan (AB521)

Casdatifan is a small-molecule inhibitor of hypoxia-inducible factor 2-alpha (HIF-2a), a master switch that turns on hundreds of genes in response to low oxygen levels. In a majority of people with the most common form of kidney cancer (clear cell renal cell carcinoma; ccRCC), genetic anomalies result in the dysregulation of this master switch and transformation of normal kidney cells into cancerous ones.

Casdatifan was designed to provide deep and durable inhibition of the HIF-2a pathway. Early clinical studies have shown high response rates and a low primary progression rate relative to clinical benchmarks, warranting further investigation in late-stage studies. Casdatifan, which is administered in pill form once daily, has a safety profile that allows it to be investigated in combination with other treatments.

The casdatifan development strategy is designed to generate evidence needed to establish casdatifan as a backbone therapy so that every ccRCC patient has the opportunity to benefit from casdatifan across each line of therapy. In addition to partner-operationalized studies, Arcus is investigating casdatifan across multiple cohorts in the ARC-20 platform study, alone and in combination with other potential new treatment options, including in the:

- First-line setting with cohorts evaluating casdatifan plus zimberelimab, an anti-PD-1 (ongoing); and casdatifan plus zimberelimab and ipilimumab, an anti-CTLA-4 (ongoing)
- Second-line setting with a cohort evaluating casdatifan plus cabozantinib in immunotherapy (IO)-experienced patients (ongoing)
- Late-line setting with a cohort evaluating casdatifan plus a TKI in both HIF-2a inhibitor-experienced and HIF-2a inhibitor-naive patients (planned)

Arcus is also enrolling patients for PEAK-1, the global Phase 3 study evaluating casdatifan plus cabozantinib versus cabozantinib in IO-experienced metastatic ccRCC. Arcus expects to complete enrollment in PEAK-1 and to initiate a Phase 3 study in first-line metastatic ccRCC by year-end 2026.

Casdatifan is an investigational molecule. Approval from any regulatory authority for its use has not been received, and its safety and efficacy have not been established. Taiho has development and commercial rights in Japan and other countries in Asia, excluding China. Arcus Biosciences holds full rights to casdatifan everywhere else globally.

About Punitamig (BNT327/BMS986545)

Punitamig is a novel investigational bispecific antibody, jointly developed by BioNTech and BMS, combining two complementary, validated mechanisms in oncology into one single molecule. Punitamig combines PD-L1 checkpoint inhibition aimed at restoring T cells' ability to recognize and destroy tumor cells with the neutralization of VEGF-A. BioNTech and BMS are currently advancing punitamig in a broad clinical trial program with more than 20 clinical trials currently ongoing or planned to evaluate punitamig either as a monotherapy or in combination with other treatment modalities targeting different oncogenic pathways in more than 10 solid tumor indications.

About Kidney Cancer

According to the American Cancer Society, kidney cancer is among the top 10 most commonly diagnosed forms of cancer among both men and women in the U.S., and an estimated 80,450 Americans will be diagnosed with kidney cancer in 2026. ccRCC is the most common type of kidney cancer in adults. If detected in its early stages, the five-year survival rate for kidney cancer is high; for patients with advanced or late-stage metastatic kidney cancer, however, the five-year survival rate is only 19%. For metastatic kidney cancer, targeted drug therapies are one of the main treatment options.

About Arcus Biosciences

Arcus Biosciences is a clinical-stage, global biopharmaceutical company focused on developing differentiated molecules for the treatment of cancer and inflammatory and autoimmune diseases. In partnership with industry collaborators, patients and physicians around the world, Arcus is expediting the development of its late-stage portfolio of first- and/or best-in-class medicines against well-characterized biological targets and pathways and studying novel, biology-driven combinations that have the potential to help people with cancer live longer. Founded in 2015, the company has advanced multiple investigational medicines into registrational clinical trials including casdatifan, a HIF-2a inhibitor for clear cell renal cell carcinoma, and quemliclustat, a small-molecule CD73 inhibitor for pancreatic cancer. For more information about Arcus Biosciences' clinical and preclinical programs, please visit www.arcusbio.com.

Arcus Forward-Looking Statements

This press release contains forward-looking statements. All statements regarding events or results to occur in the

future contained herein are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, the potential of casdatifan and pumitamig to achieve more sustained tumor control and deliver a TKI-free option in the first-line setting, statements regarding Arcus's development strategies and plans, and the timing and achievement of milestones, including the completion of enrollment in PEAK-1 and the initiation of a Phase 3 study in 1L metastatic ccRCC. All forward-looking statements involve known and unknown risks and uncertainties and other important factors that may cause Arcus's actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, risks associated with: managing Arcus's collaborations; risks associated with manufacturing or supplying casdatifan; the unexpected emergence of adverse events or other undesirable side effects with casdatifan or casdatifan-based combinations; changes in the competitive landscape for Arcus's programs; and the inherent uncertainty associated with pharmaceutical product development and clinical trials. Risks and uncertainties facing Arcus are described more fully in the "Risk Factors" section of Arcus's most recent periodic report filed with the U.S. Securities and Exchange Commission (SEC) and in other filings that Arcus makes with the SEC from time to time, which are available at www.sec.gov. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Arcus disclaims any obligation or undertaking to update, supplement or revise any forward-looking statements contained in this press release, except to the extent required by law.

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